Message

From: Ex. 6 Personal Privacy (PP)
Sent: 6/17/2021 11:30:32 AM
To: Grifo, Francesca [Grifo.Francesca@epa.gov]; Hawkins, Belinda [Hawkins.Belinda@epa.gov]; Siciliano, CarolAnn [Siciliano.CarolAnn@epa.gov]; Lalla, Sterling [lalla.sterling@epa.gov]; OIG Hotline [OIG_Hotline@epa.gov]
Subject: Ex. 5 Deliberative Process (DP)

Flag: Follow up

Dear All, Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Violations:

Ex. 5 Deliberative Process (DP)

Thanks,

Ex. 6 Personal Privacy (PP)

From: Ex. 6 Personal Privacy (PP)
Sent: Thursday, May 27, 2021 9:14 AM
To: Grifo, Francesca <Grifo.Francesca@epa.gov>; Hawkins, Belinda <Hawkins.Belinda@epa.gov>; Siciliano, CarolAnn <Siciliano.CarolAnn@epa.gov>; Lalla, Sterling <lalla.sterling@epa.gov>; OIG Hotline <OIG_Hotline@epa.gov>
Subject: Ex. 5 Deliberative Process (DP)

Dear All:

Ex. 5 Deliberative Process (DP)

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3) ***Should the team go to HASPOC to discuss the need for a 90-day oral toxicity study, chronic study, or any other study missing from the toxicity database for 1-MCP?***

ToxSAC Response: The ToxSAC recommended meeting with HASPOC to determine if additional chronic dietary and chronic inhalation studies are needed, due to the systemic endpoints (kidney and spleen histopathology) identified in the in the 90-day inhalation study and the possibility that a lower POD may be identified. The ToxSAC recommended BPPD re-evaluate the acute studies for clinical findings for portal of entry effects. The ToxSAC also suggested seeking HASPOC's recommendation on a waiver for the 90-day dermal study. For the developmental toxicity study in rats, the ToxSAC recommended that the range-finder and the definitive prenatal study be classified as unacceptable for quantitative risk assessment as

discussed above and ask the HASPOC if an additional developmental inhalation study is required. The ToxSAC also recommended that, should HASPOC recommend additional studies, the registrant meet with the BPPD team to discuss the protocols and study designs before conducting these new studies.

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The proposed Interim Registration Review Decision signed by Anne Overstreet dated 09-16-2020:
https://www.regulations.gov/document/EPA-HQ-OPP-2014-0670-0006
An excerpt of the hazard assessment summary:

A. Human Health Assessment

Hazard Characterization

The toxicological database is considered complete for characterizing hazard and assessing risk from 1-MCP. No additional studies are anticipated to be needed for registration review. All data requirements, per 40 CFR 158.2050, have been fulfilled for 1-MCP. Hazard and exposure data, agency risk assessments, and other information on this active ingredient were evaluated against standards established by FIFRA and the Agency's regulations and scientific policies (U.S. EPA, 2014). As stated in the 1-MCP FWP, it was determined that no additional data were needed for the 1-MCP registration review case. An updated human health risk assessment for 1-MCP was conducted in July 2020 in response to new product registrations to reassess the risk exposure scenarios. EPA has determined based

[1] FIFRA Section 3 product labels can be obtained from the Pesticide Product Label System website (https://ordspub.epa.gov/ords/pesticides/f?p=PPLS:1)

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on the currently approved uses and application rates, human risks associated with the pesticidal use of 1-MCP are anticipated to be negligible (U.S. EPA, 2020).

The toxicology data provided were sufficient to demonstrate that there were no foreseeable human health hazards likely to arise from the use of 1-MCP on raw agricultural commodities when applied according to the labels and in accordance with good agricultural practices. 1-MCP exhibits low acute toxicity for all routes of exposure. 1-MCP is categorized as Toxicity Category IV for acute oral toxicity, acute inhalation toxicity, and primary dermal irritation; and categorized as Toxicity Category III for acute dermal toxicity and primary eye irritation. 1-MCP is not a skin sensitizer, and no hypersensitivity incidents were observed following exposure to the active ingredient. Data and information submitted to the Agency support the conclusions that 1-MCP is not mutagenic, not subchronically toxic, and is not a developmental toxicant (U.S. EPA, 2015).

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Please let me know if you have any questions or need additional evidence.

Thank you for your times and consideration,

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